



# Prevention NOW

April 2015 - Issue No. 17

## HPTN Welcomes Three New Sites for Study Focusing on People Who Inject Drugs (PWID) in Europe, Asia



The HIV Prevention Trials Network (HPTN) welcomes three new protocol specific sites from Indonesia, Ukraine and Vietnam that will conduct a new study, [HPTN 074](#), focused on PWID. This study will determine the feasibility of a future trial that will assess whether an integrated intervention

for HIV-infected PWID combining psychosocial counseling and supported referrals for antiretroviral therapy and substance use treatment can reduce HIV transmission to their uninfected injection partners, as compared with routine care.

The new sites are the Integrated HIV Clinic at Cipto Mangunkusumo Hospital in Jakarta, Indonesia; the Ukrainian Institute on Public Health Policy in Kyiv, Ukraine; and the Health Center of Pho Yen in Thai Nguyen, Vietnam.

“We are excited to welcome these new collaborators to the growing HPTN research network,” said Nirupama Sista, director of the HPTN. “Locating areas of high HIV incidence of the injection drug epidemic has proven elusive, and remains a challenge. With the addition of these three new sites we are hoping we can determine the feasibility of conducting a trial in this population.”

“It’s exciting for us because this is the first time we will be part of a multi-site study and part of an international team. It has been a wonderful opportunity to learn from shared experiences with other sites and the HPTN coordinating and support centers,” said Vivian Go, site leader at the Health Center of Pho Yen in Vietnam. “This is important work for Vietnam, where the epidemic is concentrated among people who inject drugs and

## Registration Coming Soon!

### HPTN & IMPAACT Network Annual Meetings

June 12-19, 2015

Crystal Gateway Marriott  
1700 Jefferson Davis Highway  
Arlington, VA 22202

>>[See agenda](#)

>>[More information](#)

### **Meeting Highlight: Youth Combination Prevention Workshop**

This workshop will be hosted by the HANC Youth Prevention Research Working Group and led by Audrey Pettifor and Sybil Hosek. The session will take place on **Wednesday, June 17** at **1:30pm** and is open to all conference attendees.

## Study Updates

### [HPTN 081](#)

(in development) will evaluate the efficacy of using a broadly neutralizing antibody, VRC01, to prevent HIV infection among men and women. This clinical trial will be conducted by HPTN and the HIV Vaccine Trials Network.

### [HPTN 077](#)

has begun enrolling participants in the United States. The trial is

other key populations. The study will provide insights as to whether facilitated access to ART treatment among HIV-infected PWID can reduce HIV transmission to their injecting partners. In Vietnam, where a large proportion of HIV-infected PWID have delayed access to care, this question is of critical importance.”

Injection drug use is a major risk behavior for HIV transmission, underlying HIV epidemics in Eastern Europe and many parts of Asia. Sites in Indonesia, Ukraine and Vietnam were selected for the HPTN 074 study, in part, because these countries have HIV prevalence rates above 30% for PWID.

The key question for HPTN 074 researchers is whether and how the integrated intervention could impact HIV incidence among the uninfected partners of HIV-positive PWID. Two previous HPTN PWID trials, HPTN 037 and HPTN 058, were unable to address the impact of interventions on HIV incidence due to low incidence in both the intervention and control arms.

Across the three sites, HPTN 074 will enroll study participants in pairs: HIV-positive PWID and from one to five of their uninfected injection partners. Participants will be randomized to receive the integrated intervention or the standard of care. For those in the intervention arm of the study, participants will receive a combination of treatments and services including counseling, referral for antiretroviral therapy (ART) at any CD4 count and for substance use treatment, and social support.

“We know that PWID who are provided with risk reduction counseling and access to medication-assisted substance use treatment in HIV prevention trials have experienced very low HIV incidence,” said Bill Miller, protocol chair of HPTN 074. “In these three distinct global settings where the HIV epidemic is largely driven by injection drug use, it will be critical to identify the key elements of the integrated strategies that will be feasible, effective, and scalable at the programmatic level. We hope this will inform future trials.”

The intervention is intended to improve participant engagement and retention in treatment for HIV and substance abuse, while helping to reduce the chances of passing the virus on to their injection partners. The counseling component of the intervention will be one more way to encourage participants to enter and stay in care and help them navigate the health care system. The study team will also assess uptake, retention and possible barriers of the integrated intervention, as compared with standard of care.

The study was designed to be “real-world” focused and flexible to meet the needs of individual PWID. ART and substance use treatment will be provided at existing health care facilities – and will not be provided or directed by the study. The study will enroll participants with higher transmission potential, putting greater emphasis on HIV-positive PWID who are less familiar with ART. At recruitment, PWID will likely be at

evaluating the safety and acceptability of the long-acting injectable cabotegravir (GSK1265744 LA) among HIV-uninfected men and women in the US, Brazil, South Africa and Malawi.

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### [HPTN 076](#)

has begun enrolling participants to test the long-acting injectable formulation of rilpivirine (TMC278 LA). This study is taking place in the US, Zimbabwe and South Africa.

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### [HPTN 075](#)

has completed training at study sites this month in Johannesburg and Cape Town, South Africa. Training continues at other study sites in Kisumu, Kenya and Blantyre, Malawi. The study, which will launch soon, will assess the feasibility of recruiting and retaining MSM for HIV prevention studies in sub-Saharan Africa.

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### [HPTN 071](#)

has completed participant enrollment in both South Africa and Zambia. This spring, the team is conducting additional training in preparation for year two of the trial. During year two, the research team will introduce another component of the study – case control studies – and will continue, initiate or plan for sub-studies related to stigma, phylogenetics, adolescents, and prevention of mother-to-child transmission (PMTCT) of HIV.

different stages of readiness to engage in care, so the intervention will be tailored to an individual's personal needs.

HPTN 074 is funded by the National Institute on Drug Abuse (NIDA) and the National Institute of Allergy and Infectious Diseases (NIAID). For more information about HPTN 074, [visit the HPTN website](#).

## HPTN Research Presented at CROI 2015



HPTN presented findings from three of its studies, [HPTN 061](#), [HPTN 065](#) and [HPTN 067](#) at the [2015 Conference on Retroviruses and Opportunistic Infections \(CROI\)](#) in Seattle, Washington this week.

HPTN Principal Investigator Dr. Wafaa El-Sadr presented new HPTN 065 results ([watch video](#)) showing that financial incentives had no overall effect on viral suppression, but may influence control of HIV in some clinical settings. Read more about these results, as well as findings from other components of the study, including expanded HIV testing and a provider survey:

[HPTN 065 Overall Study Fact Sheet](#)

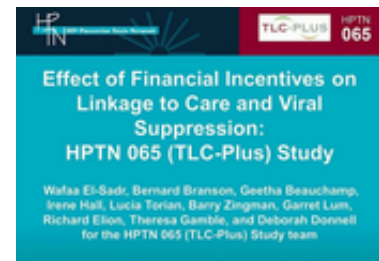
[HPTN 065 Financial Incentives Results Fact Sheet](#) (Also see [press release](#))

[HPTN 065 Expanded HIV Testing Results Fact Sheet](#)

[HPTN 065 Provider Survey Fact Sheet](#)

Preliminary results from HPTN 067 were also presented at CROI. The study team found that daily oral dosing of tenofovir disoproxil fumarate/emtricitabine (Truvada) appeared to foster better adherence, better coverage of potential sexual exposure, and more sustained use for pre-exposure prophylaxis (PrEP) by South African women study participants. The results are exciting and encouraging because contrary to other studies such as VOICE and FemPrEP, women in the daily arm of HPTN 067, had much higher adherence to Truvada. In this study, women knew that they were getting the FDA-approved Truvada in all arms. Read more about the South Africa results specifically below. The study was also conducted in New York and Bangkok, and those data will be available this summer.

## Featured Videos



### El-Sadr Delivers AVAC Webinar on HPTN 065 Results

On March 11, Dr. **Wafaa El-Sadr** presented [HPTN 065](#) study results on the feasibility of using financial incentives for linkage to care and viral suppression. An engaging discussion followed the presentation, with AVAC stakeholders connected from the US and internationally. [Watch webinar or view slides](#).

### HPTN Investigator Webinars

HPTN recently hosted two Principal Investigator webinars. In March, Drs. **Connie Celum** and **Sinead Delany-Moretlwe** presented information on the efficacy and effectiveness of PrEP in recent clinical trials, and what's ahead for the PrEP agenda. In January, Drs. **Ken Mayer**, **Steffanie Strathdee** and **Steve Shoptaw** delivered a presentation on interventions for MSMS who use stimulant drugs. To watch these and other webinars, visit the [HPTN website](#).

### Hot Off the Press

Chen I, Connor MB, Clarke W, Marzinke MA, Cummings V, Breaud A, Fogel JM, Laeyendecker O, Fields SD, Donnell D, Griffith S, Scott HM,

[HPTN 067 Cape Town Results Fact Sheet](#)  
[HPTN announcement on Cape Town data](#)

PrEP was a topic of great discussion at CROI as several highly-anticipated studies presented results. The PROUD and Ipergay studies both reported that use of Truvadaas PrEP among high-risk men who have sex with men (MSM) was highly effective. Meanwhile, the FACTS 001 study team presented disappointing data that demonstrated that the vaginal gel containing tenofovir (1%) was not effective in reducing women's risk of HIV infection. In an effort to identify other options for PrEP, the HIV Prevention Trials Network (HPTN) has a robust portfolio of studies evaluating different regimens, agents and formulations for PrEP in men and women. Read more in "[PrEP News from CROI: Findings and Implications.](#)"

The HPTN 061 study was also on display at CROI. Iris Chen gave an oral presentation ([watch video](#)) on antiretroviral screening and drug resistance. The HPTN 061 research team also presented data on the interactive, web-based tool developed to assess HIV risk among Black men who have sex with men. [Learn more about HPTN 061.](#)

The CROI conference brought together more than 4,000 international HIV/AIDS research leaders to present their work and translate clinical findings into tangible progress against the HIV pandemic. Electronic posters are available on the [CROI website](#).

## HPTN 071 (PopART) Held Annual Workshop in Lusaka



In February, the [HPTN 071](#) study team met in Lusaka, Zambia for a three-day Annual Workshop. It was a time to reflect on lessons learned from the first year of study operations and to look ahead to the future with plans for year two. Several hundred people came together for the event, from study leadership and operations staff, to site and field staff, implementing partners, scientific working groups and community health workers.

As the study team looks to year two of the study, they have plans to introduce other components, including case control studies, and to continue, initiate or plan for sub-studies related to stigma, phylogenetics, adolescents, and prevention of mother-to-child transmission (PMTCT) of

Shoptaw S, Rio CD, Magnus M, Mannheimer S, Wheeler DP, Mayer KH, Koblin BA, Eshleman SH. 2015. [Antiretroviral drug use and HIV drug resistance among HIV-infected Black men who have sex with men: HIV Prevention Trials Network 061.](#) JAIDS Journal of Acquired Immune Deficiency Syndromes. Epub ahead of print.

Closson EF, Mimiaga MJ, Sherman SG, Tangmunkongvorakul A, Friedman RK, et al. 2015. [Intimacy versus Isolation: A Qualitative Study of Sexual Practices among Sexually Active HIV-Infected Patients in HIV Care in Brazil, Thailand, and Zambia.](#) *PLoS ONE*. 10(3): e0120957. doi:10.1371/journal.pone.0120957

Hall G, Li K, Wilton L, Wheeler D, Fogel J, Wang L, Koblin B. 2015. [A Comparison of Referred Sexual Partners to Their Community Recruited Counterparts in The BROTHERS Project \(HPTN 061\).](#) *AIDS and Behavior*. doi: 10.1007/s10461-015-1005-2

Hayes R, Fidler S, Cori A, Fraser C, Floyd S, Ayles H, Beyers N, El-Sadr W, HPTN 071 (PopART) Study Team. 2015. [HIV Treatment-As-Prevention Research: Taking the Right Road at the Crossroads.](#) *PLoS One*. 12(3): e1001800. doi: 10.1371/journal.pmed.1001800

Irvin R, Vallabhaneni S, Scott H, Williams JK, Wilton L, Li X,

HIV.

## SPOTLIGHT ON THE COMMUNITY

### Bridging the Gap: Community Training on Study Protocols



During the HPTN 071 Annual Workshop in February, HPTN Community Engagement Program staff conducted a protocol review skills-building training entitled, *How to Review a Protocol and Provide Feedback*, for Community Advisory Board representatives

from each of the twelve Zambian communities participating in the HPTN 071 study.

The training, which has now been conducted in India, Malawi, South Africa, the US and Zambia since its development in 2007, is designed to equip community representatives with the necessary skills and knowledge to provide constructive and productive feedback on study protocol documents.

“It was wonderful to watch the CAB members critically think through the sections of the protocol from the perspective of how the study will impact study participants and the broader community. As they combed through the training protocol they began to recognize why it is so essential for community representatives to respond to requests for community feedback as protocols are being developed,” said Rhonda White, Senior Community Program Manager at HPTN.

Community feedback throughout the life cycle of a clinical trial is critical, particularly during the protocol development stage. As protocols are being developed in the HPTN, we seek community feedback to ensure that the trials have scientific merit; are responsive to public health concerns; address local concerns; are culturally-relevant and culturally-sensitive; and provide maximal benefit and minimal risk to the community and trial participants. The protocol review training enables bi-directional dialogue between the community and study team, and helps to ensure productive feedback and timely implementation of trials.

Buchbinder S, on behalf of HPTN 061. [Examining Levels of Risk Behaviors among Black Men Who Have Sex with Men \(MSM\) and the Association with HIV Acquisition](#). *PLoS One*. 10(2):e0118281. doi: 10.1371/journal.pone.0118281

Roman Isler M, Golin C, Wang J, Hughes J, Justman J, Haley D, Kuo I, Adimora A, Chege W, Hodder S; HIV Prevention Trials Network (HPTN064) Women’s HIV Seroincidence Study (ISIS). 2015. [Venues for Meeting Sex Partners and Partner HIV Risk Characteristics: HIV Prevention Trials Network \(HPTN064\) Women’s HIV Seroincidence Study \(ISIS\)](#). *AIDS and Behavior*. Epub ahead of print.

Metzger DS, Donnell D, Celentano DD, Jackson JB, Shao Y, Aramrattana A, Wei L, Fu L, Ma J, Lucas GM, Chawarski M, Ruan Y, Richardson P, Shin K, Chen RY, Sugarman J, Dye BJ, Rose SM, Beauchamp G, Burns DN; HPTN 058 Protocol Team. 2015. [Expanding Substance Use Treatment Options for HIV Prevention With Buprenorphine-Naloxone: HIV Prevention Trials Network 058](#). *JAIDS Journal of Acquired Immune Deficiency Syndromes*. 68(5):554-61

Safren SA; Mayer KH; Ou S; McCauley M; Grinsztejn B; Hosseinipour MC; Kumarasamy N; Gamble T; Hoffman I; Celentano D; Chen YQ; Cohen MS; for the HPTN 052 Study

## Empowering the Front Line



Nearly 700 community HIV care providers, or CHiPs, are key players in the implementation and success of HPTN 071 (PopART) in the field. The study in South Africa and Zambia is assessing whether HIV can be prevented at the community level, rather than solely at the

patient-clinic level, and field activities are expected to continue through 2017. To deliver the services of the PopART Intervention package, the CHiPs were trained on home-based HIV counselling and testing, providing health education, screening for TB and sexually transmitted diseases, providing and following up on referrals to the health center, the HPTN 071 protocol, and Good Clinical Practice for field staff.

One of those CHiPs who was hired and trained at the Desmond Tutu TB Centre in South Africa is **Gaynore Leteshia Antas Pieterston** (on right in picture above). As a CHiP, she demonstrated dedication to her work and to the community, leading to her promotion to Field Supervisor. She now manages a team of 14 CHiPs in the community.

“When I was a CHiP, the Desmond Tutu TB Centre encouraged us to always do our best so that we can develop our skills because there are always opportunities to grow,” said Pieterston, “so I was motivated in such a way that I worked hard as a CHiP and moved up in position to become a Field Supervisor later down the road.”

In her daily work, Pieterston ensures that field teams have the support needed to deliver the PopART Intervention package in the community. She conducts home evaluations of the CHiPs’ performances and provides feedback for improvement. Pieterston believes CHiPs are making an impact in the community.

“CHiPs are really helping the community in so many ways,” said Pieterston. “They are bringing the clinic to the community and to the houses. They are taking away stigma by delivering the PopART Intervention package to everyone. They support community members who are HIV-positive and even those who test negative. Sometimes just by listening to a client it really makes a change, so they are of great help to the community.”

Field staff are from the communities where they work, so they understand the challenges their clients face. Being a CHiP can be rewarding, but it’s also a challenging job. Field staff have had to walk kilometers each day,

Team. 2015. [Adherence to Early Antiretroviral Therapy: Results from HPTN 052, A Phase III, Multinational Randomized Trial of ART to Prevent HIV-1 Sexual Transmission in Serodiscordant Couples](#). *JAIDS Journal of Acquired Immune Deficiency Syndromes*. doi: 10.1097/QAI.0000000000000593.

Sugarman J, Stalter R, Bokoch K, Liu T, Donnell D. 2015. [Positive Social Impacts Related to Participation in an HIV Prevention Trial Involving People Who Inject Drugs](#). *IRB: Ethics & Human Research*. 37(1):17-19.

## Upcoming Conferences

### [ICHA:](#)

May 25-26

London, United Kingdom

### [ICPIC:](#)

June 16-19

Geneva, Switzerland

### [Adherence 2015:](#)

June 28-30

Miami, FL

### [IAS](#)

July 19-22

Vancouver, Canada

**Late-breaker deadline: 5/20**

### [USCA](#)

Sept. 10-13

Washington, DC

### [ISSTD](#)

Sept. 13-16

Brisbane, Australia

sometimes in baking heat, sometimes in cold, wet weather. They have to adjust their hours to work evenings and weekends in order to reach more families at home. Pieterse maintains a positive attitude about the challenges she's faced. "I have gone through difficult times but I always remember what my colleague said to me: 'If you plant your seeds, water your plants, take care of your environment, tend to your plant daily, you will reap good fruit' and that reminds me to continue to work hard," she said.

Pieterse continues to manage a large group of CHiPs who are spread across one of the participating communities, which is a big responsibility, and says she feels very proud to be in such a critical role: "The Desmond Tutu TB Centre gave me an opportunity to empower myself."

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## HPTN Leaders Receive Awards



**Ward Cates** is the recipient of the 2015 Allan Rosenfield Award for Lifetime Contributions to International Family Planning. Cates is Distinguished Scientist and President Emeritus at FHI 360 and an Executive Committee member of HPTN and has served as President of Family Health International (1994-2012). He has also worked at the U.S. Centers for Disease Control. [Read more.](#)



**Myron Cohen** was honored with the Faculty Service Award by the UNC-Chapel Hill General Alumni Association for groundbreaking HIV/AIDS research related to HPTN 052 revealing treatment strategies for limited transmission of the deadly virus. Over the decades of Cohen's research, UNC's infectious-disease group has achieved a top-10 ranking among AIDS programs. [Read more.](#)



**Sten Vermund** was presented the Martin Luther King, Jr. Award at Vanderbilt University for his achievements to improve public health in the U.S. and the world. Vermund's achievements demonstrate his commitment to marginalized populations globally. He is known for seeking to understand and listen to underserved populations and meet the gaping needs of the disenfranchised. [Read more.](#)

### [15th European AIDS Conference:](#)

Oct. 21-24  
Barcelona, Spain

### [APHA:](#)

Oct.31-Nov. 4  
Chicago, IL

### [ICASA:](#)

Nov. 8-13  
Hammamet, Tunisia

### [International Conference on HIV/AIDS, STDs & STIs:](#)

Nov. 30-Dec. 2  
Atlanta, GA

### [National HIV Prevention Conference](#)

Dec. 6-9  
Atlanta, Georgia

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